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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/555,950	08/17/2000	Josef Burg	HUBR-1159	9456

24972 7590 09/09/2004  
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EXAMINER
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AUDET, MAURY A

ART UNIT	PAPER NUMBER
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1654

DATE MAILED: 09/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/555,950

Applicant(s)

BURG ET AL.

Examiner

Maury Audet

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 24 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 88-99, 101, 103 and 104 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 88-99, 101, 103 and 104 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 06/14/2004.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

#### ***Response to Arguments/Amendment filed in Request for Continued Application (RCE)***

This action is in response to the papers filed 06/14/2004. Claims 88-99, 101, and 103-104 are pending. Applicant's arguments have been considered, but are not found persuasive. Applicants only argument of record (Response of 1/20/04) rely solely on the teachings of Nimtz, to assert that the other prior art references do not inherently teach Applicant's EPO composition. Again, this is not found persuasive because, first of all, Nimtz had been dropped as a reference between the First Action (9/9/03) and Final Rejection (4/20/04) and secondly, the results of Nimtz were based on tests carried out in BHK cells, rather than EPO cells, the latter which Applicant's invention is based on (as indicated in the Office Action of 9/9/03). [It is noted that Applicant has amended the claims to delete that the EPO composition is isolated from CHO cells; however, this does not change the scope of the claims since the claims, as read in light of/described in the specification, remain drawn to an EPO composition isolated from CHO cells].

#### ***Claim Rejections - 35 USC § 102/103***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 88-99, 101, and 103-104 are rejected under 35 U.S.C. 102(b) and/or (e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Watson et al. (Glycobiology, 1994, 4(2): 227-37), Takeuchi et al. (Proc. Natl. Acad. Sci., October 1989, 86: 7810-7822), Blumen et al. (US 5,459,031), Akamatsu et al. (US 4,745,099), and Strickland et al. (US 5,856,298).

The claims are drawn to an EPO composition which has been isolated from CHO cells.

The cited references all disclose EPO compositions which appears to be identical to the presently claimed EPO composition (see, e.g., an EPO composition which claims the structural characteristics of EPO isolated from CHO cells), since the reference EPO compositions were all isolated from CHO cells. As to the CITED references, Applicant has not persuasively pointed out where in the specification Applicant's process of isolating EPO from CHO cells could have produced an EPO composition which is any different structurally than any other EPO composition isolated from CHO cells in the past (see references). Consequently, and absent evidence to the contrary that Applicant has produced an INHERENTLY DIFFERENT EPO from CHO cells composition, the claimed EPO composition appears to be anticipated by the reference.

In the alternative, even if the claimed EPO composition (from CHO cells) is not identical to the referenced EPO compositions (from CHO cells) with regard to some unidentified

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characteristics (and in view of EP-A-0 267 678 (Integrated Genetics, Inc.), if needed to teach serum free medium production of EPO), the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced EPO compositions are likely to inherently possess the same characteristics of the claimed EPO composition, since both were isolated through the same process. Thus, the claimed EPO composition would have been obvious to those of ordinary skill in the art within the meaning of USC 103.

Accordingly, the claimed invention as a whole was at least *prima facie* obvious, if not anticipated by the reference, especially in the absence of sufficient, clear, and convincing evidence to the contrary.

Please note that the Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether Applicants' claimed EPO composition differs and, if so, to what extent, from that of the discussed reference. Therefore, with the showing of the reference, the burden of establishing non-obviousness by objective evidence is shifted to the Applicants.

### *Conclusion*

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. In line with the references above, Takeuchi et al. #2 (Glycobiology. 1991 Sep;1(4):337-46. Review) also teach EPO from CHO cells, including repeating tetraantennary units (see e.g. Table I, CHOb; entire document).

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No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maury Audet whose telephone number is 571-272-0960. The examiner can normally be reached from 7:00 AM – 5:30 PM, off Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached at 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.

MA  
9/3/04



CHRISTOPHER R. TATE  
PRIMARY EXAMINER